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U.S. Food and Drug Administration

New York District
850 Third Avenue, Brooklyn, New York 11232

Telephone: [718] 340-7000 [Ext 5532]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 18, 1997

Gene Santiago, President
Empire Managed Care Inc.
6 Executive Boulevard
Yonkers, New York 10701

re: 59-NYK-97

Dear Mr. Santiago:

During a May 14 to 21, 1997 inspection of your facility our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for the manufacturing, processing, packing, or holding of drugs (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause containers of Liquid Oxygen U.S.P. filled by your firm to be adulterated within the meaning of section 501(a)(2)(B) of the Food, Drug and Cosmetic Act (the Act).

At the conclusion of the inspection the investigator presented the enclosed Inspectional Observations (Form FDA 483) to Mr. Kenneth Ciuzio, Vice President and discussed the findings. The following deviations pertaining to the filling of medical gases were found:

1. Failure to assure identity and strength of each incoming vessel of liquid oxygen. The testing by the supplier that results in the Certificate of Analysis placed on the Liquid Oxygen Delivery Tag for each bulk vessel is not witnessed by your firm, therefore you must perform an identity test on each vessel prior to placing the incoming product into use. The reliability of the supplier's Certificate of Analysis is not periodically validated by your firm through a supplier audit, or through your sampling and complete purity ar l identity testing by a third party.
2. Failure to adequately maintain complete records of the periodic calibration of the [redacted] oxygen analyzer used to test the completed filled patient units. Your Packing Control Records did not record the calibration until after May 14, 1997. Your analyzer is acceptable for identity testing of oxygen. Testing for purity of oxygen requires methods or equipment that is the same as or equivalent to the U.S.P., that is, an accuracy to within 0.1%. The manual for the [redacted] analyzer states it has accuracy only to within 2%.

3. Your process of introducing nitrogen into the returned patients' units has caused the testing of these units to require full U.S.P. testing of each vessel, utilizing methods or equipment that is the same as or equivalent to the U.S.P., that is, an accuracy to within 0.1%. You do not have proper test equipment to conduct full U.S.P. testing.
4. Failure to perform and document visual inspections on oxygen cryogenic vessels to assure that the volume or contents gauge is satisfactory, the containers are free of damage, have correct valve and connection assemblies, are free of debris, oil or grease, and have the proper oxygen labels.
5. Failure to maintain written procedures for training of employees responsible for the handling and testing of the medical oxygen, written procedures for testing and inspection of the incoming oxygen for identity and strength, performing the visual inspections of the oxygen cryogenic vessels prior to fill, and the filling and testing of the vessels.
6. Failure to store components and compressed gas vessels in a secure area. The storage area for the supplier's bulk tank of cryogenic oxygen and E size compressed tanks had holes in the fence large enough for an E size tank.

The above cited violations should not be regarded as all inclusive. It is your responsibility to ensure that all requirements of the Federal Food Drug and Cosmetic Act and all regulations promulgated thereunder, are being satisfied for all products subject to these requirements.

We request that you take prompt action to correct these deviations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the status of the specific steps you have taken or intend to take to correct the noted violations. You should report in writing those steps taken that may have already been witnessed by or explained to our investigator during the inspection. Include an explanation of each step being taken to prevent the recurrence of similar violations and a timetable for correction.

Your reply should be sent to the Food and Drug Administration, New York District Office, at the above address, Attention: William Friedrich, Compliance Officer.

Sincerely,

Alonza E. Cruse
Acting District Director
New York District